

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2032002	(X3) Date Survey Completed 08/29/2019
Name of Provider or Supplier Dermatology And Mohs Surgery Center	Street Address, City, State 920 Lawn Ave, Sellersville, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the Mohs technician, the laboratory failed to establish a complete competency assessment procedure to assess the competency of 2 of 3 clinical consultants and 1 of 2 technical supervisors for Mohs micrographic surgery examinations from 11/03/2017 to the day of survey. Findings Include: 1. On the day of survey, 08/29/2019, the laboratory could not provide a written procedure to assess the competency of 2 of 3 clinical consultants and 1 of 2 technical supervisors for Mohs slide examinations from 11/03/2017 to 08/29/2019. 2. The Mohs technician confirmed the finding above on 08/29/2019 around 9:00 am.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and interview with the Mohs technician, the laboratory failed to follow their quality assurance (QA) policy for Mohs micrographic</p>

surgery examinations in 2018. Findings Include: 1. The Quarterly Lab Quality Assessment Policy states, "An overall quality assessment of the Mohs lab and its procedures will be done on a quarterly bases by the lab director and any complaints or issue will be addressed at that time". 2. On the day of survey, 08/29/2019, review of QA documentation revealed, the laboratory performed and documented QA of the Mohs micrographic laboratory, April, August and December of 2018. 3. The Mohs technician confirmed on 08/29/2019 around 9:15 am that QA was not documented on a quarterly bases.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observation of reagents and interview with the Mohs technician, the laboratory failed to label The Davidson Marking Systems dyes (4 of 4 bottles) and unlabeled marking dye aliquots (3 of 3 bottles) with open and expiration dates required, prior to use from 2018 to the date of survey. Findings Include: 1. While on tour of the laboratory, 08/29/2019, it was observed that the following reagent bottles were not labeled with open and expiration dates prior to use: - 1 of 1 Yellow The Davidson Marking Systems dye. - 1 of 1 Blue The Davidson Marking Systems dye. - 1 of 1 Red The Davidson Marking Systems dye. - 1 of 1 Black The Davidson Marking Systems dye. - 3 of 3 aliquots of unlabelled marking dye. 2. The laboratory could not provide documentation of the open and expiration dates of the above reagents prior to use. 3. The LD could not provide a procedure describing steps taken when obtaining reagents from manufacturers that do not specify an expiration date. 4. The LD confirmed the findings above on 05/21/2019 around 10:00 am.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on the review of patient test reports and interview with Mohs technician, the laboratory failed to include on test reports the location where Mohs micrographic slides were examined from 11/03/2017 to the date of survey. Finding Include: 1. On the day of survey, 08/29/2019, a review of some test reports (5 of 5) revealed the test reports did not include the correct address where the slides were examined. 2. Slides

were read at Dermatology and Mohs Surgery Center, 920 Lawn Avenue, Suite 6. Sellersville, PA 18960 but, 2003 Lower State Rd, Doylestown, PA 18901 were listed on final Mohs reports. 3. The Mohs technician confirmed the findings above on 08/29 /2019 around 9:10 am.